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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,851	05/28/2002	Horst Rapp	HMN 2 0021	8437

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,851

Applicant(s)

RAPP ET AL.

Examiner

Shaojia A Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on January 23, 2004 wherein claims 1-19 have been amended since claim 1 has been amended.

Currently, claims 1-20 are pending in this application.

Claims 1-20 as amended now are examined on the merits herein.

Applicant's amendment (amended claim 1) filed on January 23, 2004 with respect to the objection to claims 1-19 for minor informalities, of record stated in the Office Action dated September 22, 2003 has been fully considered and is found persuasive since claim 1 has been amended to remove these expressions. Therefore, this said objection is withdrawn.

Applicant's amendment filed on January 23, 2004 with respect to the rejection of claims 1-19 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitations, i.e., "disinfection" in claim 1, "may be", "in particular", and "such as" in claims 3-6, 8, and 10 of record stated in the Office Action dated September 22, 2003 have been fully considered and found persuasive to remove the rejection as to these indefinite recitations.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-20 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling the instant compounds for treating particular skin diseases disclosed in the specification (page 3), does not reasonably provide enablement for treating any “diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases”, essentially for reasons of record stated in the Office Action dated September 22, 2003.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method of treating any “diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases and disinfection”.

The relative skill of those in the art: The relative skill of those in the art is high.

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The breadth of the claims: The instant claims are deemed very broad since these claims reads on treating any diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses any "diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases and disinfection", a great numbers of skin diseases, which may be involved various, many possible, and different etiologies. Thus, the skilled artisan would view that the treatment of all skin diseases by administering the particular compound herein, i.e., tosylchloramide, is highly unpredictable.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects and toxicity generated by administering tosylchloramide for treating any skin disease herein except for retroviral HIV diseases.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary:

It is noted that the specification merely provides the working examples for treating several particular skin diseases at page 10-14 of the specification, e.g., itching caused by mosquito bites (Example 4 at page 10), Herpes Labialis, neurodermatitis with herpes superinfection (Example 5 at page 11).

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad treatment of any skin diseases except for retroviral HIV diseases recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of treating any skin diseases recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test the instant compound for treating any skin diseases encompassed in the instant claims, with no assurance of success.

Response to Argument

Applicant's arguments filed January 23, 2004 with respect to this rejection have been fully considered but are not deemed persuasive as to lack of full scope of enablement.

First, Applicant asserts that the Examiner mischaracterizes the recitation of claim 1 by rejecting that claim 1 recite that the use of tosylchloramide(s), tosylchloramide salt(s), their derivatives, decomposition products and mixtures thereof for the treatment of ANY diseases (see Applicant's remarks at page 6). Contrary to Applicant's assertion, the Examiner's position is that the instant claims reads on treating any diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases (see the previous Office Action page 2-3), not any diseases. Note that Applicant admits that "it simply recites the use of these compounds for treatment of diseases of the skin and mucous membranes, organs and tissues without reciting specific diseases" (emphasis added).

Secondly, Applicant argument that claims must be read in light of the specification and thus would not be required to engage in undue experimentation to practice the invention is not found persuasive. As noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example.

As discussed in the previous Office Action, the pharmaceutical art is **unpredictable**, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy

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the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses any "diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases and disinfection", a great numbers of skin diseases, which may be involved various, many possible, and different etiologies. Thus, the skilled artisan would view that the treatment of all skin diseases except for retroviral HIV diseases by administering the particular compound herein, i.e., tosylchloramide, is highly unpredictable.

Applicant asserts that "it is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art." and "Applicants submit that the scope of the claims are commensurate with the scope of the disclosure and that the open-endedness of claim 1 is limited by what a person skilled in the art would understand to be workable, without the need for undue experimentation" (emphasis added). Nonetheless, it is noted that the specification merely provides the working examples for treating several particular skin diseases at page 10-14 of the specification, e.g., itching caused by mosquito bites (Example 4 at page 10), Herpes Labialis, neurodermatitis with herpes superinfection (Example 5 at page 11).

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad treatment of any skin diseases except for retroviral HIV diseases recited in the instant claims, given the fact that the claims encompassing a great numbers of skin diseases, which may be involved various, many possible, and different etiologies. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of treating any skin diseases recited in the instant claims suitable to

practice the claimed invention. Working example is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

As pointed out in the previous Office Action, *Genentech*, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 9-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record stated in the Office Action dated September 22, 2003.

Applicant's remarks filed on January 23, 2004 with respect to this rejection of record stated in the previous Office Action have been fully considered but are not deemed persuasive.

Applicant asserts that

"The term "derivative" and "decomposition products" with respect to tosylchloramide(s) are clear and definite to a skilled artisan. Specifically, "derivative" refers to closely related chemical compounds derived tosylchloramide(s) via known reactions. Likewise, the term "decomposition

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products" refers to products derived from tosylchloramidet(s) via well known decomposition reactions"

As discussed in the previous Office Action, the recitations, one of ordinary skill in the art would clearly recognize that "derivatives" and "decomposition products" encompass many, various, and possibly groups substituting tosylchloramide, given their **broadest** reasonable interpretation. Moreover, one of ordinary skill in the art would understand that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physiological effects and functions. Thus, it is unclear what would be encompassed as "their derivatives" and "decomposition products" in the claim.

Thus, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "derivatives" and "decomposition products".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-13, 17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wakeman (3,317,540) for reasons of record stated in the Office Action dated September 22, 2003.

Wakeman discloses that tosylchloriaamide(s) and its known derivatives are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection (see col.1 and col.3 lines 53-56). Wakeman discloses the pharmaceutical compositions of tosylchloriaamide(s) in a form, a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O?W or W/O-emulsion (see col. 2 line 32 to col.3 38). Wakeman's method inherently treats the instant particular skin diseases, since Wakeman's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, Wakeman anticipates claims 1-6, 9-13, 17, and 20.

Claims 1-10 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 197 12 565 for reasons of record stated in the Office Action dated September 22, 2003.

DE 197 12 565 discloses that tosylchloriaamide(s) and its known derivatives such as Chloramin T are useful in a pharmaceutical composition by topical administration to skin broadly and hair and thus useful in treating skin diseases herein (see Table at page 5 and claims 1-16). DE 197 12 565 also discloses the effective

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amounts of the pharmaceutical compositions of tosylchloriaamide(s) (see Table at page 5 and claims therein). The method of DE 197 12 565 inherently treats the instant particular skin diseases, since the method steps therein are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, DE 197 12 565 anticipates claims 1-10, and 20.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Vandeveld et al (WO 91/07876) for reasons of record stated in the Office Action dated September 22, 2003.

Vandeveld et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandeveld et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-13 at page 9-20). Vandeveld's method inherently

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treats the instant particular skin diseases, since Vandeveldel's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, Vandeveldel anticipates claims 1-20.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Harwardt et al (DE 41 37 544) for reasons of record stated in the Office Action dated September 22, 2003.

Harwardt et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4). Harwardt's method inherently treats the instant particular skin diseases, since Harwardt's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or

unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, Harwardt anticipates claims 1-20.

Response to Argument

Applicant's arguments filed January 23, 2004 with respect to all prior art rejections under 35 U.S.C. 102(b) of record stated in the Office Action dated September 22, 2003 have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant asserts that Wakeman does not teach applying compounds to the skin or other tissue. Contrary to Applicant's assertion, Wakeman discloses that tosylchloriaamide(s) and its known derivatives are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection (see col.1 and col.3 lines 53-56). Nowhere is Wakeman's treatment limited to only inanimate objects.

Applicant also asserts that Vandeveld is directed only as being applied to inanimate objects. Nowhere is Vandeveld's treatment limited to only inanimate objects. Applicant also asserts that Harwardt et al has not disclosed or suggested a method for treating skin diseases. However, given the fact that the instant claims read on any skin

diseases/conditions with the open-endedness as Applicant's admission, the disclosure of Harwardt et al that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair, reads on the instant broad claims.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

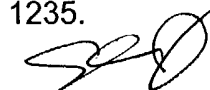
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The

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fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

A handwritten signature in black ink, appearing to be 'S. Anna Jiang', with a long horizontal stroke extending to the right.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 3, 2004